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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,033	06/15/2001	Jean-Louis Imbach	06171..105026(NOV 1005)	4301

7590

07/16/2002

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/883,033

Applicant(s)

IMBACH ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-174 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-174 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-155 drawn to 3'-beta-L-nucleoside compounds and analogs classified in class 536, subclasses 26.7, 26.8, 27.1, 28.4, and 4.1. as well as class 544, subclasses 242 and 262.
- II. Claims 157, 158 and 164 are drawn to 3'-amino acid substituted Pyrimidine nucleoside compounds and compositions classified in classes 536 and 514, subclasses 28.4 and 49 respectively.
- III. Claims 165-174 are drawn to a method for treating HBV in a host with a compound of Group I classified in class 514, subclass 894.

The inventions are distinct from each other for the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions I and II have different core structures. The compound of Group II is a Pyrimidine nucleoside containing amino acid at the 3' and 5' positions whereas the compound of Group I is a beta-L- nucleoside with several substituents other than amino acids. The structural core for the compounds of Group I and Group II are divergent. A search for compounds of Group I will not

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necessitate the same search for Group II. Further, a reference rendering compounds of Group I obvious will not render compounds of Group II obvious. Applicant is not entitled to examination of multiple compounds. This would indeed place an undue burden upon the examiner in charge of this application.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case HBV can be treated with a different L-nucleoside (USPN 5,565,438, abstract, col. 2, lines 26-42)

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case compounds of Group II (similar core structure) can be used to treat a different disease, namely infection by Epstein-Barr virus (USPN 5,587,362, see summary of the invention).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification, restriction for examination purposes as indicated is proper.

It would indeed impose an undue burden upon the examiner in charge of this application if the instant restriction and species requirements are not advanced as set forth herein.

In the event the applicants elect the inventions of Group I or of Group III, applicants are further required to respond to the following species requirement.

Should applicants elect the inventions of Group I, the following species requirement contingent upon the specific identity of the variable "X" in the carbohydrate portion of the structure's core is required:

Species A, Purine nucleosides wherein the variable "X" is oxygen, classified in class 536, subclasses 26.7 and 27.1.

Species B, Pyrimidine nucleosides wherein the variable "X" is oxygen, classified in class 536, subclasses 26.8 and 28.4.

Species C, Pyrimidine S-glycoside nucleosides wherein the variable "X" is S or SO₂, classified in class 536, subclass 4.1.

Species D, Purine and Pyrimidine carbocyclic nucleoside analogs, wherein the variable "X" is CH₂, classified in class 544, subclasses 256 and 261.

Should applicants elect the inventions of Group III, the following species requirement contingent upon the specific identity of the variable "X" in the carbohydrate portion of the structure's core is required:

Species A, Purine nucleosides wherein the variable "X" is oxygen, classified in class 514, subclasses 45+.

Species B, Pyrimidine nucleosides wherein the variable "X" is oxygen, classified in class 514, subclasses 49+.

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Species C, Pyrimidine S-glycoside nucleosides wherein the variable "X" is S or SO₂,
classified in class 514, subclass 24.

Species D, Purine and Pyrimidine carbocyclic nucleoside analogs, wherein the variable
"X" is CH₂, classified in class 514, subclasses 256 and 261.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

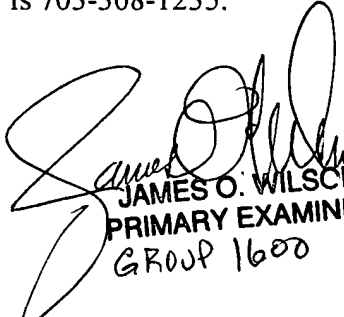
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
July 11, 2002


JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600